KEY DIFFERENCES BETWEEN KENNEDY-DORGAN & GREGG-SMITH-COLLINS

Kennedy-Dorgan **Pharmaceutical Market Access & Drug Safety Act (S.2328)**	**Gregg-Smith-Collins** **Safe Importing of Medical Products and Rx Therapies Act (Safe IMPORT Act)**
Allows importation of potentially hazardous unapproved prescription drugs. Permits the importation of drug products with a different active ingredient, a "related" active ingredient, or different active ingredients. For personal importation, FDA may waive virtually any potential approval condition, including whether the drug is FDA-approved or manufactured in an FDA-inspected facility. Permits the importation of certain biological products approved under section 505, such as insulin and growth hormone.	Importation limited to FDA-approved drugs manufactured in FDA-approved facilities. Also prohibits importation of controlled substances and biological products (including those approved under section 505).
Lacks critical safety provisions. Has only the barest provisions to protect American consumers from rogue Internet pharmacies; does not allow FDA to restrict ports of entry or to require importers to provide advance notice of any shipment to ensure that all incoming commercial drug shipments are inspected.	Protects consumers from rogue Internet pharmacies by establishing federal licensing requirements and penalties for all Internet pharmacies that illegally conduct or solicit business in the U.S. The FDA will also be given strong authority over imported prescription drugs as they now have in ensuring the safety of imported food: all foreign and domestic businesses engaged in importation will be required to register, maintain certain records, provide prior notice of commercial shipments, and submit to inspections by the FDA.
Automatically permits importation from 19 countries beyond Canada without prior FDA review – even if FDA has evidence of harm to American consumers.	Importation could be extended by FDA to up to 15 E.U. countries. FDA would have 3 years to prepare a comprehensive report for Congress identifying which of the 15 E.U. countries importation could be safely extended.
Unworkable and constitutionally questionable "forced sales" provisions. Requires drug manufacturers to sell unlimited quantities of their drugs to foreign retailers at whatever price that foreign country stipulates, likely violating both the Takings Clause of the Fifth Amendment and the Patent Clause of Article I of the U.S. Constitution.	Such provisions are unnecessary and unenforceable. Canadian businesses are allowed to purchase FDA-approved product from the 15 identified E.U. countries for resale to U.S. consumers.
Provides inadequate resources to the FDA and will likely divert funds from other critical domestic drug review and enforcement activities. Not only are foreign wholesalers & exporters exempt from having to pay any user fees, but the arbitrary 1% cap means that the current $1 billion worth of drugs imported annually from Canada would generate a mere $10 million in FDA resources	Establishes a new, uncapped "user fee" program paid for by all foreign and domestic businesses engaged in importation to ensure that the FDA has sufficient resources to monitor the safety of these drugs.
Unworkable time-frame jeopardizes safety of American consumers. FDA must develop, implement, collect user fees, and conduct inspections to permit importation of drugs from Canada within 90 days and from 19 other countries within a mere 12 months.	FDA would have 1 year to develop, implement, collect user fees, and conduct inspections to permit commercial importation from Canada. FDA would have up to 3 years to do the same for the 15 E.U. countries.

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Imposes unreasonably higher burdens on U.S. pharmacies, while leaving foreign wholesalers & exporters largely unregulated. Registration requirements apply only to U.S. wholesalers and U.S. and Canadian pharmacies; wholesalers & exporters from Canada & the other 19 countries are not required to register or confirm in advance their credentials for exporting large quantities of drugs to the U.S.	All foreign businesses – whether in Canada or in any of the 15 permitted countries -- engaged in the importation of prescription drugs to the U.S. will be required to register with the FDA..
Forces Canadian pharmacies to cut off their supply or increase prices for American consumers. High financial obligations ($10,000 user fee, semiannual inspection fees) and unreasonably intrusive operational requirements (record and facility inspections as often as every day) will compel most Canadian pharmacies to restrict sales to American consumers.	All foreign businesses – whether in Canada or in any of the 15 permitted countries – engaged in the importation of prescription drugs to the U.S. will be required to pay a user fee. The significantly greater number of persons subject to the user-fee ensures that the fee will manageable and more fairly apportioned.
Fails to provide important information to American consumers. Allows imported drugs to be mixed with domestic drugs, and does not require that imported drugs be labeled as such.	Gives American consumers the ability to make an informed choice about the source of their prescription drugs, by requiring importers to keep their imported drugs separate from other drugs and to disclose whether a drug is imported.
Will increase drug costs and slow down approval of new medicines here in the U.S. Requiring the FDA to review foreign-intended drugs will take time & resources that could otherwise go to reviewing new medicines intended for the U.S. market. Additionally, manufactures would likely pass on the cost of these applications on the American consumer in the form of higher drug prices.	No such problem under the Safe IMPORT Act, because only FDA-approved drugs manufactured in FDA-approved facilities are permitted to be imported into the U.S.